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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,300	04/09/2004	Paul R. Hinton	011823-012611US	1900

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EXAMINER

CROWDER, CHUN

ART UNIT	PAPER NUMBER
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1644

MAIL DATE	DELIVERY MODE
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09/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/822,300

Applicant(s)

HINTON ET AL.

Examiner

Chun Crowder

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07/19/2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-8, 13, 16, 28-31, and 38-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,5,13,16,28-31,38 and 39 is/are allowed.
- 6) ☒ Claim(s) 3, 6-8, 40 and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

1. Applicant's amendment, filed on July 19, 2007, is acknowledged.

Claims 4, 9-12, 14-15, 17-27, and 32-37 have been canceled.

Claims 1-3 have been amended.

Claim 1-3, 5-8, 13, 16, 28-31, and 38-41 are pending and under consideration.

2. This Office Action will be in response to applicant's arguments, filed on July 19, 2007.

The rejections of record can be found in the previous Office Action, mailed on December 30, 2005, July 14, 2006, and April 13, 2007.

3. The amendment, filed on July 19, 2007, is considered non-compliant because it fails to meet the requirements of 37 CFR § 1.121, as amended on June 30, 2003 (see *68 Fed. Reg. 38611*, Jun. 30, 2003).

The amendment is non-compliant because the "Listing of Claims" is not a complete listing of all of the claims. Specifically, claims 32 and 33 have been canceled. However, claims 32 and 33 have not been included in the Listing of Claims.

In the interest of compact prosecution, this Office Action is set forth.

Applicant is required to submit a "Listing of Claims" that is compliant with the requirements of 37 CFR 1.121.

4. Upon further consideration as well as applicant's amendment to the claims, the prior rejections under 35 U.S.C. 112, 1st paragraph, set forth in Section 7A and 7B of the previous Office Action mailed on April 13, 2007, have been withdrawn.

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5. In light of applicant's filing of Terminal Disclaimers that are in compliance with 37 CFR 3.73(b) on July 19, 2007 and applicant's assertion that the present application and the copending USSN 10/966,673 are commonly owned, the prior provisional obviousness-type double patenting rejections have been withdrawn.

6. This is a **New Ground of Rejection**. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 3, 6-8, 40 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 3, 6-8, 40 and 41 recite a heavy chain constant region at least 95% identical to that of a naturally occurring class IgG antibody”.

Applicant's arguments have been fully considered but have not been found persuasive.

Applicant argues that such antibodies do not require undue experimentation because one skill in the art would know how to make the claimed antibodies based on the teachings of the instant specification. Further, applicant argues that the specification provides examples of amino acid substitutions in the Fc region other than the claimed position 250 and 428 that can alter FcRn binding and serum half-life of antibodies. Thus, applicant argues that skilled artisan would know how to make the claimed antibody comprising a variable region from daclizumab and a heavy chain constant region that is at least 95% identical to a naturally occurring IgG with substitutions at positions 250 and 428 in combination with other known substitutions in the Fc region.

This is not found persuasive for following reasons:

Contrary to applicant's assertion that one skilled artisan would know how to make the claimed antibody with a heavy chain constant region that is at least 95% identical to a naturally occurring IgG, it is noted that the claims, as written, broadly encompass any substitutions in the Fc region in combination with position 250 and 428. However, the instant specification does not provide sufficient guidance and directions regarding how to make and use the claimed antibody comprising a variable region from daclizumab and a heavy chain constant region that is at least 95% identical to IgG with amino acid substitutions in addition to position 250 and 428. One skill in the art would not know how to make the claimed antibody that has the functions of altered FcRn binding affinity and/or serum half-life.

The previous Office Action mailed on July 19, 2007:

"The state of the art at the time the invention was made recognized that certain positions of the Fc region of an IgG antibody, e.g. 310 and 435, must be maintained in order to preserve the sharp pH dependence of the FcRn/IgG interaction. For example, Martin et al. (Molecular Cell 2001. 7:867-877. Reference 68 on IDS) show that mutation in position 435 of the Fc region reduces the binding to FcRn indicating reduced serum half-lives in vivo (see entire article, particularly Results on pages 867-875).

Further, the instant application disclose that not all mutations the Fc region result in desired function, e.g. mutations in position 314 of an antibody show reduced binding to human FcRn (see page 66 of the instant specification). Therefore, only certain positions in the Fc region of an IgG antibody can be altered for enhanced binding to FcRn and increased serum half-life."

Given the extensive variation permitted by the instant claim language, the skilled artisan would not reasonably predict such antibody with a heavy chain constant region at least 95% identical to that of a naturally occurring IgG with amino acid substitutions in addition to position 250 and 428 to have the same function as the instant claimed invention.

In view of the quantity of experimentation necessary, the limited working example, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

8. Claims 1, 2, 5, 13, 16, 28-31, 38, and 39 appear to be free of the prior art.
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is 571-272-8142. The examiner can normally be reached on 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Chun Crowder

Patent Examiner

September 6, 2007

Maheer M. Haddad
MAHER M. HADDAD
PRIMARY EXAMINER